

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	<b>09/911,692</b>	Group Art Unit:	1644
Confirmation No.:	8484	Examiner:	R. Schwadron
Filed:	25 July 2001		
Applicant:	Darrell R. ANDERSON et al.		
For:	Expression and Use of Anti-CD20 Antibodies		

Mail Stop **Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In compliance with the requirements and provisions of 37 C.F.R. §§ 1.56, 1.97, and 1.98, applicant cites the documents listed on the Form PTO-1449 that accompanies this paper. Copies of the cited documents, except for U.S. patent documents, are also provided. Applicant does not represent that a search has been conducted or that the cited documents are prior art against the claims in this application.

This disclosure statement is filed after a first action on the merits under the provisions of 37 C.F.R. § 1.97(c)(2). Applicant requests that the Director charge the IDS fee (§ 1.17(p)) of **\$180**, as well as any additional fee required to support consideration of this statement, to our **Deposit Account No. 18-1260**.

Applicant requests that the examiner indicate consideration of the cited references.

Respectfully submitted,

/David L. Fitzgerald/

David L. Fitzgerald, Reg. No. 47,347  
Attorney for Biogen Idec Inc.

SIDLEY AUSTIN LLP  
1501 K Street, N.W.  
Washington, DC 20005  
tel. (202) 736-8818  
fax (202) 736-8711

<b>INFORMATION DISCLOSURE STATEMENT</b>	Docket No.	27693-01009	Serial No:	<b>09/ 911,692</b>
	Inventor(s):	D.R. ANDERSON <i>et al.</i>	Examiner:	R. Schwadron
	Filed:	25 July 2001	Art Unit:	1644

### U.S. PATENT DOCUMENTS

INITIAL	INDEX	DOCUMENT	DATE	NAME	CLASS	SUB.	FILING DATE
	<b>D1</b>	4,831,175	16 May 1989	Gansow			
	<b>D2</b>	5,099,069	24 Mar 1992	Gansow			
	<b>D3</b>	5,124,471	23 Jun 1992	Gansow			
	<b>D4</b>	5,246,692	21 Sep 1993	Gansow			
	<b>D5</b>	5,286,850	15 Feb 1994	Gansow			
	<b>D6</b>	5,460,785	24 Oct 1995	Rhodes			
	<b>D7</b>	2003/ 0095963 A1	22 May 2003	Anderson			
	<b>D8</b>	2004/ 0167319 A1	26 Aug 2004	Teeling			

### FOREIGN PATENT DOCUMENTS

INITIAL	INDEX	DOCUMENT	DATE	COUNTRY	CLASS	SUB.	TRANSLATION	
	<b>D9</b>	0 669 836 B1	7 Mar 1996	EP				
	<b>D10</b>	0 752 248 A1	8 Jan 1997	EP				
	<b>D11</b>	87/ 02671 A1	7 May 1987	WO				
	<b>D12</b>	89/ 00999 A1	9 Feb 1989	WO				
	<b>D13</b>	93/ 02108 A1	4 Feb 1993	WO				
	<b>D14</b>	00/ 27428 A1	18 May 2000	WO				
	<b>D15</b>	00/ 27433 A1	18 May 2000	WO				
	<b>D16</b>	01/ 10460 A1	15 Feb 2001	WO				

EXAMINER	DATE CONSIDERED
Initial if a citation is considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.	
Form PTO-1449 (modified)	SHEET 1 OF 5

<b>INFORMATION DISCLOSURE STATEMENT</b>	Docket No.	27693-01009	Serial No:	09/ 911,692
	Inventor(s):	D.R. ANDERSON <i>et al.</i>	Examiner:	R. Schwadron
	Filed:	25 July 2001	Art Unit:	1644

### OTHER DOCUMENTS

INITIAL	INDEX	CITATION
	<b>D17</b>	Anderson D.R. et al. <i>Biochem. Soc. Trans.</i> 25(2): 705-08, 1997. Targeted anti-cancer therapy using rituximab, a chimaeric anti-CD20 antibody (IDEC-C2B8) in the treatment of non-Hodgkin's B-cell lymphoma.
	<b>D18</b>	Armitage J.O. et al. <i>J. Clin. Oncol.</i> 16(8): 2780-95, 1998. New approach to classifying non-Hodgkin's lymphomas: clinical features of the major histologic subtypes. Non-Hodgkin's Lymphoma Classification Project.
	<b>D19</b>	Berinstein N.L. et al. <i>Ann. Oncol.</i> 9: 995-1001, 1998. Association of serum rituximab (IDEC-C2B8) concentration and anti-tumor response in the treatment of recurrent low-grade or follicular non-Hodgkin's lymphoma.
	<b>D20</b>	Beychok S. (in) <i>Cells of Immunoglobulin Synthesis</i> , B. Pernis et al., eds. New York: Academic Press, 1979, 69-88. Comparative aspects of <i>in vitro</i> and cellular assembly of immunoglobulins.
	<b>D21</b>	Buchsbaum D.J. et al. <i>Cancer Res.</i> 52: 637-642, 1992. Improved delivery of radiolabeled anti-B1 monoclonal antibody to Raji lymphoma xenografts by predosing with unlabeled anti-B1 monoclonal antibody.
	<b>D22</b>	Carrasquillo J.A. et al. <i>J. Nucl. Med.</i> 26: 67, abst. no. 276, 1985. Improved imaging of metastatic melanoma with high dose 9.2.27 In-111 monoclonal antibody.
	<b>D23</b>	Chinn P.C. et al. <i>Int. J. Oncol.</i> 15(5): 1017-25, Nov. 1999. Preclinical evaluation of 90Y-labeled anti-CD20 monoclonal antibody for treatment of non-Hodgkin's lymphoma.
	<b>D24</b>	Chinn P.C. et al. <i>Proc. Ann. Mtg. Am. Assn. Cancer Res.</i> 40: 574, abst. no. 3786, 1999. A <sup>90</sup> Y-labeled anti-CD20 monoclonal antibody conjugated to MX-DTPA, a high-affinity chelator for yttrium.
	<b>D25</b>	Cogliatti S.B. et al. <i>Sw. Med. Weekly</i> 192: 607-17, 2002. Who is <i>WHO</i> and what was <i>REAL</i> ?
	<b>D26</b>	Davis T.A. et al. <i>Clin. Cancer Res.</i> 5(3): 611-15, 1999. Therapy of B-cell lymphoma with anti-CD20 antibodies can result in the loss of CD20 antigen expression.
	<b>D27</b>	Davis T.A. et al. <i>Proc. Ann. Mtg. Amer. Assn. Cancer Res.</i> 39: 435, abst. no. 2964, 1998. Therapy of B cell lymphoma with anti-CD20 can result in relapse with loss of CD20 expression.
	<b>D28</b>	Dillman R.O. <i>J. Clin. Oncol.</i> 12(7): 1497-1515, 1994. Antibodies as cytotoxic therapy.

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
Initial if a citation is considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.	
Form PTO-1449 (modified)	
SHEET 2 OF 5	

<b>INFORMATION DISCLOSURE STATEMENT</b>	Docket No.	27693-01009	Serial No:	09/ 911,692
	Inventor(s):	D.R. ANDERSON <i>et al.</i>	Examiner:	R. Schwadron
	Filed:	25 July 2001	Art Unit:	1644

INITIAL	INDEX	CITATION
	<b>D29</b>	Grillo-López A.J. IBC Int'l. Conference on Antibody Engineering, La Jolla, December 1994. IDEC-C2B8 chimeric antibody and IDEC-Y2B8 radiolabeled antibody phase I and II studies in patients with non-Hodgkin's lymphoma (abstract of presentation).
	<b>D30</b>	Grillo-López A.J. et al. <i>Ann. Oncol.</i> 7(3 Suppl.): 57, abst. no. 195, 1996. Treatment (rx) of relapsed non-Hodgkin's lymphoma (NHL) using the 90-yttrium (90-Y) labeled anti-CD20 monoclonal antibody (MAB) IDEC-Y2B8: a phase I clinical trial (PI CT).
	<b>D31</b>	Grillo-López A.J. et al. <i>Antibody Immunoconj. Radiopharm.</i> 8: 60, abst. no. 10, 1995. Treatment options for patients with relapsed low-grade or follicular lymphoma: the role of IDEC-C2B8.
	<b>D32</b>	Grillo-López A.J. et al. <i>Blood</i> (86(10 Suppl. 1): 55a, abst. no. 207, 1995. Phase I study of IDEC-Y2B8: 90-yttrium labeled anti-CD20 monoclonal antibody therapy of relapsed non-Hodgkin's lymphoma.
	<b>D33</b>	Grillo-López A.J. et al. <i>Br. J. Haematol.</i> 93(Suppl. 2): 283, abst. no. 1072, 1996. IDEC-C2B8 chimeric anti-CD20 antibody (MAB): safety and clinical activity in the treatment of patients (PTS) with relapsed low-grade or follicular (IWF:A-D) non-Hodgkin's lymphoma (NHL).
	<b>D34</b>	Horning S.J. et al. <i>Blood</i> 100(11 part 1): 357a, abst. no. 1385, 2002. Rituximab treatment failures: tositumomab and Iodine I 131 tositumomab (Bexxar®) can produce meaningful durable responses.
	<b>D35</b>	IDEC Pharmaceuticals Corp. and Genentech, Inc., Product insert for RITUXAN® approved by U.S. Food and Drug Administration on 26 November 1997.
	<b>D36</b>	Janakiraman N. et al. <i>Blood</i> 92(10 Suppl. 1): 337a, abst. no. 1384, Nov. 1998. Rituximab: correlation between effector cells and clinical activity in NHL.
	<b>D37</b>	Kinoshita T. et al. <i>J. Clin. Oncol.</i> 16(12): 3916, Dec. 1998. CD20-negative relapse in B-cell lymphoma after treatment with Rituximab.
	<b>D38</b>	Maloney D.C. et al. <i>Blood</i> 90(6): 2188-2195, 1997. IDEC-C2B8 (Rituximab) anti-CD20 monoclonal antibody therapy in patients with relapsed low-grade non-Hodgkin's lymphoma.
	<b>D39</b>	Maloney D.G. et al. <i>Blood</i> 88(10: Suppl. 1): 637a, abst. no. 2635, 1996. The anti-tumor effect of monoclonal anti-CD20 antibody (mAb) therapy includes direct anti-proliferative activity and induction of apoptosis in CD20 positive non-Hodgkin's lymphoma (NHL) cell lines.

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
Initial if a citation is considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.	
Form PTO-1449 (modified)	
SHEET 3 OF 5	

<b>INFORMATION DISCLOSURE STATEMENT</b>	Docket No.	27693-01009	Serial No:	09/ 911,692
	Inventor(s):	D.R. ANDERSON <i>et al.</i>	Examiner:	R. Schwadron
	Filed:	25 July 2001	Art Unit:	1644

INITIAL	INDEX	CITATION
	<b>D40</b>	Maloney D.G. et al. <i>J. Clin. Oncol.</i> 15(10): 3266-3274, Oct. 1997. IDEC-C2B8: results of a phase I multiple-dose trial in patients with relapsed non-Hodgkin's Lymphoma.
	<b>D41</b>	Maloney D.M. et al. <i>Blood</i> 84(8): 2457-66, 1994. Phase I clinical trial using escalating single-dose infusion of chimeric anti-CD20 monoclonal antibody (IDEC-C2B8) in patients with recurrent B-cell lymphoma.
	<b>D42</b>	McLaughlin P. et al. <i>Blood</i> 92(10 Suppl. 1): 414a-415a, abst. no. 1712, Nov. 1998. Efficacy controls and long-term follow-up for relapsed or refractory, low-grade or follicular (R-LG/F) NHL.
	<b>D43</b>	McLaughlin P. et al. <i>J. Clin. Oncol.</i> 16(8): 2825-2833, Aug. 1998. Rituximab chimeric-anti-CD20 monoclonal antibody therapy for relapsed indolent lymphoma: half of patients respond to a four-dose treatment program.
	<b>D44</b>	McLaughlin P. et al. <i>Oncology</i> 12(12): 1763-81, 1998. Clinical status and optimal use of rituximab for B-cell lymphomas.
	<b>D45</b>	Non-Hodgkin's Lymphoma Pathologic Classification Project. <i>Cancer</i> 49(10): 2112-35, 1982. National Cancer Institute sponsored study of classifications of non-Hodgkin's lymphomas.
	<b>D46</b>	Pietersz G.A. et al. <i>Immunol. Cell. Biol.</i> 65(2): 111-25, 1987. The use of monoclonal antibody conjugates for the diagnosis and treatment of cancer.
	<b>D47</b>	Piro L.D. et al. <i>Ann. Oncol.</i> 10: 655-61, 1999. Extended Rituximab (anti-CD20 monoclonal antibody) therapy for relapsed or refractory low-grade or follicular non-Hodgkin's lymphoma.
	<b>D48</b>	Press O.W. <i>Cancer J. Sci. Amer.</i> 4(Suppl 2): S19-S26, Jul. 1998. Prospects for the management of non-Hodgkin's lymphomas with monoclonal antibodies and immunoconjugates.
	<b>D49</b>	Teeling J.L. et al. <i>Blood</i> 104:1793-1800, 2004. Characterization of new human CD20 monoclonal antibodies with potent cytolytic activity against non-Hodgkin lymphomas.
	<b>D50</b>	Teeling J.L. et al. <i>J. Immunol.</i> 277: 362-71, 2006. The biological activity of human CD20 monoclonal antibodies is linked to unique epitopes on CD20.
	<b>D51</b>	White C.A. et al. <i>Ann. Oncol.</i> 10(3 Suppl): 64, abst. no. 215, 1999. Radioimmunotherapy of relapsed or refractory non-Hodgkin's lymphoma (NHL): IDEC-Y2B8 phase I/II <sup>90</sup> yttrium trial.
	<b>D52</b>	White C.A. et al. <i>Ann. Rev. Med.</i> 52: 125-45, 2001. Antibody-targeted immunotherapy for treatment of malignancy.
	<b>D53</b>	White C.A. et al. <i>Blood</i> 87(9): 3640-49, 1996. Radioimmunotherapy of relapsed B-cell lymphoma with Yttrium 90 anti-idiotypic monoclonal antibodies.

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
Initial if a citation is considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.	
Form PTO-1449 (modified)	
SHEET 4 OF 5	

<b>INFORMATION DISCLOSURE STATEMENT</b>	Docket No.	27693-01009	Serial No:	<b>09/ 911,692</b>
	Inventor(s):	D.R. ANDERSON <i>et al.</i>	Examiner:	R. Schwadron
	Filed:	25 July 2001	Art Unit:	1644

INITIAL	INDEX	CITATION
	<b>D54</b>	White C.A. et al. <i>Eur. J. Cancer</i> 35: S57, abst. no. 107, 1999. Zevalin™ radioimmunotherapy of relapsed or refractory non-Hodgkin's lymphoma.
	<b>D55</b>	Witzig T. et al. <i>Blood</i> 90(10 Suppl. 1): 586a, abst. no. 2606, 1997. IDEC-Y2B8 <sup>90</sup> yttrium anti-CD20 radioimmunotherapy of relapsed non-Hodgkin's lymphoma (NHL): interim results of a phase I/II trial.
	<b>D56</b>	Witzig T.E. et al. <i>J. Clin. Oncol.</i> 17(12): 3793-3803, 1999. Phase I/II trial of IDEC-Y2B8 radioimmunotherapy for treatment of relapsed or refractory CD20(+) B-cell non-Hodgkin's lymphoma.
	<b>D57</b>	Witzig T.E. et al. <i>J. Clin. Oncol.</i> 20: 2453-63, 2002. Randomized controlled trial of yttrium-90-labeled ibritumomab tiuxetan radioimmunotherapy versus rituximab immunotherapy for patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma.
	<b>D58</b>	Witzig T.E. et al. <i>Blood</i> 94(10 Suppl. 1): 631a, abst. no. 2805, 1999. Prospective randomized controlled study of ZEVALIN™ (IDEC-Y2B8) radioimmunotherapy compared to rituximab immunotherapy for B-cell NHL: report of interim results.

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
Initial if a citation is considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.	
Form PTO-1449 (modified)	
SHEET 5 OF 5	